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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,469	07/07/1999	AUSTIN GERARD SMITH	06999.0001-0	5288

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EXAMINER	
PARAS JR, PETER	

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 07/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/348,469	Applicant(s) SMITH ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24,26-29,32-34 and 41-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,26-29,32-34 and 41-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice To Comply* .

DETAILED ACTION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Peter Paras, Jr in Art Unit 1632.

Applicant's amendment received on 9/13/01 has been entered. Claims 22, 28 29, 32 and 34 have been amended. New claims 43-46 have been added. Claim 25 has been cancelled. Claims 22-24, 26-29, 32-34, and 41-46 are pending and are under current consideration.

Specification

The disclosure is objected to because of the following informalities: on page 31 the heading "Claims" should be "We claim".

Appropriate correction is required.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With

Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. *Any* response to this Office Action, which fails to meet all of these requirements, will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Applicant is requested to return a copy of the attached Notice to Comply with the response.

To avoid damage to a CRF by irradiation, a reply to a notice to comply with the sequence rules should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)
2. Mailed to: **U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202**
3. Mailed by Federal Express, United Parcel Service or other delivery service to: **U. S. Patent and Trademark Office, 2011 South Clark Place, Customer Window, Box Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, Virginia 22202**
4. Hand Carried directly to the Customer Window at: **2011 South Clark Place, Crystal Plaza Two, Lobby, Room 1B03, Box Sequence, Arlington, Virginia 22202**

Priority

Applicant's claim of priority to 08/537,765 now US patent 6,150,169 is denied.

The parent application fails to fulfill the requirements of 35 U.S.C 120 by not meeting

the requirements of the first paragraph of 35 U.S.C. 112, particularly written description and new matter, necessary to support the claims of the instant application. In particular the claim limitations as follows are not described in the instant specification: X comprises a splice acceptor site, and Y comprises a polyadenylation signal. See the rejections under 35 U.S.C. 112. 1st paragraph below.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 22-29, 32-34 and 41-42 under 35 U.S.C. 112, first paragraph, has been withdrawn.

Applicant's arguments with respect to claims 22-29, 32-34 and 41-42 have been considered but are moot in view of the new ground(s) of rejection.

The following are new grounds of rejection under 35 U.S.C. 112, first paragraph:

New Matter

Claims 22-29, 32-34 and 41-46 as originally filed, amended, or newly added are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 22 is directed to a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse cell genome, comprising transforming the mouse cell with a random gene trap vector comprising a DNA construct, wherein the DNA construct (k) lacks a promoter, and comprises the sequence: 5' X-A-P-B-Q-C-Y 3' in which X comprises a splice acceptor sequence; Y comprises a polyadenylation signal; P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. Claims 23-24, 26-29, 41, and 43-44 depend from claim 22.

Claim 32 is directed a DNA construct lacking a promoter and comprising the sequence: 5' X-A-P-B-Q-C-Y 3' in which X comprises a splice acceptor sequence; Y comprises a polyadenylation signal; P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. Claims 33-34, 42, and 45-46 depend from claim 32.

The specification provides no implicit or explicit support for the following limitations recited in claims 22 and 32 (and claims that depend there from): **the DNA construct (k) lacks a promoter, X comprises a splice acceptor sequence and Y comprises a polyadenylation signal.**

Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 C.F.R. 1.121(b)(2)(iii); also see the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes, "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure.*

Claims 22-29, 32-34 and 41-46 as originally filed, amended, or newly added are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse cell genome and expressing said heterologous gene coding sequence, comprising the step of transforming the mouse cell with a random gene trap vector comprising a DNA construct, wherein the DNA construct (k) lacks a promoter, and (ii) comprises the sequence 5' X-A-P-B-Q-C-Y 3', in which X comprises a splice acceptor sequence; Y comprises a polyadenylation signal; P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The claims are further directed to a mouse cell comprising a heterologous gene coding sequence inserted by the above method and a DNA construct for randomly inserting a heterologous gene sequence into a mouse cell genome, wherein the DNA construct (k) lacks a promoter, and (ii) comprises the sequence 5' X-A-P-B-Q-C-Y 3' as above.

The specification has taught a DNA construct comprising the sequence 5' X-A-P-B-Q-C-Y 3', wherein X and Y comprise nucleotide sequences that are homologous to an endogenous gene in a mouse cell, P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The specification has also taught the creation of transgenic mice comprising the same construct, wherein the construct was introduced into ES cells to produce chimeric mice. However, the specification has not taught the DNA construct comprising the sequence 5' X-A-P-B-Q-C-Y 3', wherein X comprises a splice acceptor site and Y comprises a polyadenylation signal. Moreover, the

specification has not taught a method of inserting a heterologous gene coding sequence into an endogenous mouse cell genome using the same DNA construct or a mouse cell comprising the same DNA construct. The instant specification has not even provided a working example directed to a mouse cell transfected *in vitro* with the claimed DNA construct. As such, in light of the teachings of the specification, which are directed to the creation of transgenic mice, there do not appear to be any other disclosed uses for the claimed DNA construct or method than for the creation of transgenic mice.

As a first issue, the instant specification has not provided no guidance that would enable the skilled artisan to practice the claimed invention. In particular, the construct embraced by the claims is not disclosed in the instant specification. More particularly, the claim limitations of X comprising a splice acceptor site and Y comprising a polyadenylation signal are not disclosed in the specification. As such the claimed construct has not been taught. Moreover, the skilled artisan would not know how to use the claimed invention because it has not been disclosed in the instant specification. The guidance and working examples provided by the instant specification are directed to making and using a different DNA construct. While the instant specification is directed to the creation of transgenic mice, use of the claimed construct in that context has not been disclosed. However, if one of skill were contemplating the creation of transgenic mice with the claimed construct the issues of unpredictability related to such are discussed in detail below.

As a second issue, claims 22-24, 26-27, 41, and 43-44 are directed to a method for inserting a heterologous gene coding sequence into an endogenous gene in a

mouse genome and expressing said heterologous gene coding sequence. Such a method is interpreted to read on a method for creating a transgenic mouse when read in light of the teachings of the specification. See the specification at pages 1, 6, and 8, for example. Since the preamble of the claim 22 is directed to insertion of a heterologous gene coding sequence into an endogenous gene, the claim is further interpreted to fall in to the realm of embryonic stem (ES) cell technology, wherein heterologous nucleotide sequences are inserted into endogenous gene sequences by homologous recombination. Presently, ES cell technology is generally limited to the mouse system, wherein only embryonic stem cells have successfully demonstrated germline transmission. See Mullins et al (Journal of Clinical Investigation, 1996) on page S38 and throughout the document. Germline transmission of a transgene is important because the chimeric mice that are generated must be bred to homozygosity in order to observe a phenotype resulting from incorporation of the transgene into the host mouse's genome. Since only ES cells can transmit through the germline of a mouse, all other cells are found to be unpredictable and not enabled for the creation of a transgenic mouse. Further, the instant specification has not provided any guidance that supports the creation of a transgenic mouse with cells other than ES cells. Even further with respect to claim 44 although the claim recites mouse embryonic stem cells, the instant specification has not provided any working examples that demonstrate the creation of a single transgenic mouse whose genome comprises the DNA construct recited in the claims, wherein X comprises a splice acceptor site and Y comprises a polyadenylation signal. As such claim 44 is not enabled. Given the unpredictability of creating

transgenic mice with cells other than ES cells it would have required undue experimentation to create a transgenic mouse by the method without a reasonable expectation of success.

Claims 28-29 are directed to mouse cells comprising the DNA construct encompassed by the claims, having the sequence 5' X-A-P-B-Q-C-Y 3', wherein X comprises a splice acceptor site and Y comprises a polyadenylation signal. The claims as written do not recite isolated cells, and can be interpreted to read on a transgenic mouse when taken with the teachings of the specification. As the instant specification has not taught the creation of a single transgenic mouse comprising the recited construct as mentioned above or a cultured cell comprising the recited construct the claims are not enabled.

Claims 22-24, 26-29, 41, and 43-44 are directed to a method for inserting a heterologous gene coding sequence into an endogenous gene in a mouse cell genome and mouse cells produced by the method. The method requires inserting a heterologous gene coding sequence into an endogenous gene and is interpreted to read on insertion of a heterologous coding sequence by homologous recombination. The claims however do not require that the recited construct comprise sequences that are homologous to the endogenous gene sequence. As such it is unpredictable if the heterologous coding sequence can be inserted into an endogenous gene because heterologous gene sequences (for example, transgenes) unless specifically designed for homologous recombination will randomly integrate into a host genome. Random integration does not necessarily include integration into endogenous genes. See Wall

and Houdebine below. If by chance random integration resulted in incorporation of the claimed construct into an endogenous gene, the specification has not provided any guidance for determining which endogenous gene has incorporated the claimed construct. More over the claims as written would require nothing more than trial and error experimentation to successfully introduce the claimed DNA construct into an endogenous gene. Given the lack of recited homologous sequences in the claims it would have required undue experimentation for one of skill in the art to insert a heterologous coding sequence into an endogenous gene in a mouse cell genome as claimed without a reasonable expectation of success.

Claims 32-34, 42, and 45-46 are directed to a DNA construct comprising the sequence 5' X-A-P-B-Q-C-Y 3', wherein X and Y comprise nucleotide sequences that are homologous to an endogenous gene in a mouse cell, P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The claims also recited the intended use limitation "for randomly inserting a heterologous gene sequence into a mouse cell genome". The intended use limitation is interpreted to read on creating a transgenic mouse as is consistent with the teachings of the specification. The instant specification has failed to teach the creation of a single transgenic mouse comprising the claimed construct. As the specification fails to provide any relevant teachings or guidance with regard to the production of a transgenic mouse whose genome comprises the claimed construct, one of skill would not be able to rely on the state of the transgenic art for an attempt to produce such transgenic mice. This is because the

state of the art of transgenics is not a predictable art with respect to transgene behavior and the resulting phenotype. While the state of the art of transgenics is such that one of skill in the art would be able to produce transgenic mice comprising a transgene of interest, it is not predictable if the transgene would be expressed at a level and specificity sufficient to cause a particular phenotype. For instance, the level and specificity of expression of a transgene as well as the resulting phenotype of the transgenic animal are directly dependent on the specific transgene construct. The individual gene of interest, promoter, enhancer, coding, or non-coding sequences present in the transgene construct, the specificity of transgene integration into the genome, for example, are all important factors in controlling the expression of a transgene in the production of transgenic animal which exhibits a resulting phenotype. This observation is supported by Wall (Theriogenology, 1996) who states that "[o]ur lack of understanding of essential genetic control elements makes it difficult to design transgenes with predictable behavior." See page 61, last paragraph. See also Houdebine (Journal of Biotechnology, 1994) who discloses that in the field of transgenics, constructs must be designed case by case without general rules to obtain good expression of a transgene (page 275, column 1, 1st paragraph); *e.g.*, specific promoters, presence or absence of introns, *etc.* As such guidance is lacking in the instant specification, it fails to teach the production of a single transgenic mouse whose genome comprises the claimed construct. Given the lack of guidance provided by the instant specification for the production of a single transgenic mouse comprising the claimed construct it would have required undue experimentation for the skilled artisan to

make and use the invention as claimed. This aspect of the rejection may be overcome by removing the intended use limitation clause, "for randomly inserting a heterologous gene sequence into a mouse cell genome".

Given the lack of guidance, relevant teachings, and the absence of working examples, it would have required undue experimentation for the skilled artisan to make and use the invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 22-24, 26, 28-29, 32-33, and 43-46 as originally filed, amended, or newly added are rejected under 35 U.S.C. 102(e) as being anticipated by Tessier-Lavigne et al (US 6,248,934).

The claims are directed to a method of inserting a heterologous gene coding sequence into an endogenous gene in a mouse cell genome and expressing said heterologous gene coding sequence, comprising the step of transforming the mouse cell with a random gene trap vector comprising a DNA construct, wherein the DNA construct (k) lacks a promoter, and (ii) comprises the sequence 5' X-A-P-B-Q-C-Y 3', in which X comprises a splice acceptor sequence; Y comprises a polyadenylation signal; P is an internal ribosome entry site (IRES); Q is the heterologous gene sequence, including a translation start codon; and A, B and C are, separately, optional linked sequences. The claims are further directed to a mouse cell comprising a heterologous gene coding sequence inserted by the above method and a DNA construct for randomly inserting a heterologous gene sequence into a mouse cell genome, wherein the DNA construct (k) lacks a promoter, and (ii) comprises the sequence 5' X-A-P-B-Q-C-Y 3' as above.

Tessier-Lavigne et al teach a DNA construct comprising the following elements from 5' to 3': a splice acceptor site, an IRES sequence, a heterologous nucleotide sequence, and a polyadenylation signal, wherein the construct is promoterless. See figure 1a, column 2 lines 25-31, and column 5 lines 29-33. Tessier-Lavigne et al also teach that the construct integrates into a gene in a cell, wherein the cells may be mouse embryonic stem cells. See columns 7-8 as well as the claims.

Conclusion

No claim is allowed.

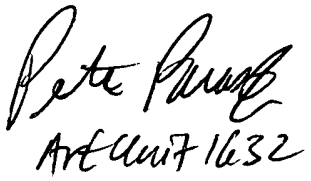
Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 305-2758.

Peter Paras, Jr.

Art Unit 1632



Application No.:09/348,469

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

[X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

[X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

[X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

[ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

[ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

[ ] 7. Other: _____

Applicant Must Provide:

[X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

[x] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
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